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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 02D-0407]

**Diagnostic X-Ray Field Size; Revocation of Compliance Policy Guide 7133.17**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled "Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)." This CPG is no longer necessary because the agency amended the Diagnostic X-Ray Systems Federal Performance Standard to include the minimum x-ray field size.

**DATES:** The revocation is effective *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411, or FAX your request to 301-827-0482.

A copy of the CPG may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory

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Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA issued the CPG entitled “Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)” on October 1, 1980. This CPG addresses the different requirements for minimum field size for spot-film and fluoroscopic modes of operation for fixed source-image receptor distance (SID) fluoroscopic x-ray systems. This CPG includes a statement that such systems that do not have stepless adjustment would be required to provide a minimum field size of 125 square centimeters or less during fluoroscopy and spot-film radiography.

In the **Federal Register** of May 3, 1993 (58 FR 26401), FDA amended the diagnostic X-ray systems Federal performance standard to incorporate a provision for spot-film devices used on fixed SID fluoroscopic systems. Specifically, 21 CFR 1020.31(h)(4)(i) requires that for spot-film devices used on fixed SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters.

Given the current diagnostic X-ray systems Federal performance standard, FDA is revoking CPG 7133.17, in its entirety, to eliminate unnecessary compliance policy.

## II. Electronic Access

Before [*insert date 30 days after date of publication in the Federal Register*], a copy of the CPG may be obtained from the Internet at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgdev/cpg398-475.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg398-475.html).

Dated: 10.01.02  
October 1, 2002.



John Marzilli,  
Deputy Associate Commissioner for Regulatory Affairs.

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